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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
FORD, VANESSA L

ART UNIT	PAPER NUMBER
1645	

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19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,750	GORRINGE ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 28-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 28-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's response to the Restriction requirement and election of Group I claim, 1-5, 6-8, 10-13 and 15 filed on November 19, 2002 is acknowledged. However, in view of Applicants arguments, the Restriction requirement is withdrawn and the claims 1-20 and 28-34 will be examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-20 and 29-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. *This is a written description rejection.*

The specification broadly describes a part of their invention pharmaceutical compositions comprising Cu,Zn superoxide dismutase (Cu,Zn-SOD) of the dimeric type or a fragment, variant or derivative of Cu,Zn-SOD. The specification states that " an antigenic fragment of Cu,Zn-SOD may also be used in the vaccine formulation" and " the fragment preferably comprises a region of Cu,Zn-SOD that is in the surface of the protein, although any fragment that confers protective immunity to bacterial infection is suitable and the term "fragment" is intended to encompass any fragment against which an antibody may be raised which antibody binds intact, full-length SOD" (page 4). The

specification teaches that "mutant variants which have been modified to increase antigenicity or fusion protein derivatives between all or part of a Cu,Zn-SOD and another protein for the purposes of purification or increasing antigenicity may be also suitable for the use in pharmaceutical compositions (page 9). The specification also teaches that " vaccine components of the invention also include derivatives and variants of Cu,Zn-SOD and the term "derivative" is intended to encompass combinations of Cu,Zn-SOD with other proteins or molecules, including carbohydrates to form conjugate vaccines, the derivative retaining antigenicity such that an antibody raised against the derivative binds intact, full-length SOD. The specification teaches that the term "variant" is intended to encompass a polypeptide having an amino acid sequence that varies from that of the intact full-length SOD, but such that antibodies raised against the variant bind intact full-length SOD (page 9). Applicant has broadly described the invention as embracing any substitution, insertion or deletion change of amino acids throughout the length of the polypeptide sequence. The claimed Cu,Zn-SOD correspond to sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a variant degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 U.S.C. 112, first, paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now*

claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptide regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

None of the sequences encompassed by the claim meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

3. Claims 1-20 and 28-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-20 and 28-34 a pharmaceutical composition and vaccine for vaccination comprising a bacterial Cu, Z-superoxide dismutase (Cu,Zn-SOD) of the dimeric type, or a fragment, variant or derivative of the Cu,Zn-SOD wherein antibodies raised against said fragment, variant or derivative also bind intact full-length Cu,Zn-SOD or a nucleic acid coding for the Cu,Zn-SOD fragment, variant or derivative and a pharmaceutically acceptable carrier.

The specification is enabling only for wild-type bacterial Cu-Zn-SOD of the dimeric type as disclosed in the specification. The specification states that " an antigenic fragment of Cu,Zn-SOD may also be used in the vaccine formulation" and " the fragment preferably comprises a region of Cu,Zn-SOD that is in the surface of the protein, although any fragment that confers protective immunity to bacterial infection is suitable; and the term "fragment" is intended to encompass any fragment against which an antibody may be raised which antibody binds intact, full-length SOD" (page 4). The specification teaches that "mutant variants which have been modified to increase antigenicity or fusion protein derivatives between all or part of a Cu,Zn-SOD and another protein for the purposes of purification or increasing antigenicity may be also suitable for the use in pharmaceutical compositions (page 9). The specification also

teaches that "vaccine components of the invention also include derivatives and variants of Cu,Zn-SOD and the term "derivative" is intended to encompass combinations of Cu,Zn-SOD with other proteins or molecules, including carbohydrates to form conjugate vaccines, the derivative retaining antigenicity such that an antibody raised against the derivative binds intact, full-length SOD. The specification teaches that the term "variant" is intended to encompass a polypeptide having an amino acid sequence that varies from that of the intact full-length SOD, but such that antibodies raised against the variant bind intact full-length SOD (page 9). Applicant has broadly described the invention as embracing any substitution, insertion or deletion change of amino acids throughout the length of the polypeptide sequence. There is no guidance provided as to which amino acids can be added, deleted or substituted and the polypeptide would retain its biological function. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claims and the claims broadly encompass a significant number of inoperative species. Since the amino acid sequence of the polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar activity/utility requires a knowledge with regard to which amino acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved (i.e. expected intolerant to modification) and detailed knowledge of the ways in which the polypeptide's structure relates to function. However, the problem of the prediction of polypeptide structure from mere sequence data of a single polypeptide and in turn

utilizing predicted structural determinations to ascertain functional aspects of the polypeptide and finally what changes can be tolerated with respect thereto is extremely complex and outside of the realm of routine experimentation.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen multiple substitutions or multiple modifications of other types and the positions within the polypeptide's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any polypeptide and the result of such modifications is unpredictable based on the instant disclosure. One skilled in the art would expect any tolerance to modifications , e.g., multiple substitutions. The sequence of some polypeptides is highly conserved and one skilled in the art would not expect tolerance to any amino acid modification in such polypeptides.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to selecting other Cu,Zn-SODs

having claimed functional features, 3) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level). One of skill in the art would require guidance, in order to make or use polypeptides that are variants of bacterial Cu, Zn-Sod of the dimeric type in a manner reasonable in correlation with the scope of the claims. Without proper guidance, the experimentation to is undue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2 and 4-8 are rejected under 35 U.S.C. 102(b) as anticipated by Wilks et al *(Infection and Immunity, January 1998, p. 213-217).*

Claims 1-2 and 4-8 pharmaceutical composition and vaccine for vaccination comprising a bacterial Cu, Z-superoxidè dismutase (Cu,Zn-SOD) of the dimeric type, or a fragment, variant or derivative of the Cu,Zn-SOD wherein antibodies raised against said fragment, variant or derivative also bind intact full-length Cu,Zn-SOD or a nucleic acid coding for the Cu,Zn-SOD fragment, variant or derivative and a pharmaceutically acceptable carrier.

Wilks et al teach a pharmaceutical composition comprising wild-type sodC and iron dextran (page 216, 2nd column). Wilks et al teach also teach a pharmaceutical

composition comprising a sodC mutant from *Neisseria meningitidis* and iron dextran (page 216, 2nd column). Wilks et al teach that 24 hours after infection the majority of animals given wild-type MC58 looked ill whereas animals infected with the sodC mutant were recovering. Wilks et al teach that these studies using sodC knockout mutant have defined a role for Cu,Zn SOD in meningococcal biology, protecting organisms against exogenous superoxide challenge and the this reflected in reduced virulence of the sodC mutant in a mouse model of infection suggesting the protection against superoxide produced during host defense reactions may be important strategy enabling meningococci to survive in the course of systemic human infection (page 216, 2nd. column). The claim limitation such as "vaccine" is being viewed as a limitation of intended use.

Since the Office does not have the facilities for examining and comparing applicant's pharmaceutical composition and vaccine with the device of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the pharmaceutical composition and vaccine of the prior art does not possess the same material structural and functional characteristics of the claimed pharmaceutical composition and vaccine). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

5. Claim 9 is rejected under 35 U.S.C. 102(b) as anticipated by Wilks et al *(Infection and Immunity, January 1998, p. 213-217).*

Claim 9 is drawn to a method of preparing a pharmaceutical composition isolating a gene for a bacterial Cu, Zn-superoxide dismutase (Cu,Zn-SOD) of the

dimeric type, or a fragment, variant or derivative of the Cu, Zn-SOD wherein antibodies raised against said fragment, variant or derivative also bind intact full-length Cu,Zn-SOD; and synthesizing the Cu,Zn-SOD or fragment, variant or derivative from gene; and combining said Cu,Zn-SOD, fragment, variant or derivative with a pharmaceutically acceptable or combining said gene with a pharmaceutically acceptable carrier.

Wilks et al teaches a method of preparing a pharmaceutical composition comprising isolating and synthesizing the gene for bacterial Cu, Zn-superoxide dismutase (Cu,Zn-SOD) of the dimeric type (see the Material and Methods section, pages 214-215).

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

6. Claims 1-8 are rejected under 35 U.S.C. 102(b) as anticipated by Langford et al *(Infection and Immunity, Dec. 1996, p. 5035-5041).*

Claims 1-8 are drawn to a pharmaceutical composition and vaccine for vaccination comprising a bacterial Cu, Zn-superoxide dismutase (Cu,Zn-SOD) of the dimeric type, or a fragment, variant or derivative of the Cu,Zn-SOD wherein antibodies raised against said fragment, variant or derivative also bind intact full-length Cu,Zn-SOD

or a nucleic acid coding for the Cu,Zn-SOD fragment, variant or derivative and a pharmaceutically acceptable carrier.

Langford et al teach compositions comprising cell pellets containing Cu, Zn-superoxide dismutase obtained from *Actinobacillus pleuropnemoniae* in Tris and copper sulfate (page 5035, 2nd column). Langford et al teach compositions comprising Cu, Zn-superoxide dismutase obtained from *Actinobacillus pleuropnemoniae* on SAGE-PAGE gels (page 5036, 1st column). Langford et al teach compositions containing Cu, Zn-superoxide dismutase obtained from *Actinobacillus pleuropnemoniae* harvested from aerobic liquid culture (page 5035, 1st and 2nd column). Langford et al teach the cloning and characterization of the sodC gene that encodes Cu,Zn SOD protein (pages 5037-5039). Langford et al is that *Actinobacillus pleuropnemoniae* Cu,Zn-SOD is localized in the periplasm and Langford et al suggest that the potential to modulate the course of host-parasite interaction by dismutating exogenous superoxide offers a potential target for modulation of the course of infection by vaccines (page 5040, 1st column). Langford et al teach that *Actinobacillus pleuropnemoniae* has been associated with cilia on the respiratory epithelium and suggests that -superoxide generated by localization of inflammation resulting from superficial infection might, through the action of bacterial Cu, Zn SOD lead to production of H2O2 which in a catalase-negative strain can diffuse freely across the bacterial membrane to reach a local concentration sufficient to inhibit ciliary beating (page 5040, 2nd column).

Since the Office does not have the facilities for examining and comparing applicant's pharmaceutical composition and vaccine with the pharmaceutical

composition and vaccine of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the pharmaceutical composition and vaccine of the prior art does not possess the same material structural and functional characteristics of the claimed pharmaceutical composition and vaccine). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

7. Claim 9 is rejected under 35 U.S.C. 102(b) as anticipated by Langford et al *(Infection and Immunity, Dec. 1996, p. 5035-5041).*

Claim 9 is drawn to a method of preparing a pharmaceutical composition isolating a gene for a bacterial Cu, Zn-superoxide dismutase (Cu,Zn-SOD) of the dimeric type, or a fragment, variant or derivative of the Cu, Zn-SOD wherein antibodies raised against said fragment, variant or derivative also bind intact full-length Cu,Zn-SOD; and synthesizing the Cu,Zn-SOD or fragment, variant or derivative from gene; and combining said Cu,Zn-SOD, fragment, variant or derivative with a pharmaceutically acceptable or combining said gene with a pharmaceutically acceptable carrier.

Langford et al teach a method of preparing a pharmaceutical composition comprising isolating and synthesizing the gene for bacterial Cu, Zn-superoxide dismutase (Cu,Zn-SOD) of the dimeric type (pages 5036-5039).

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of

the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

8. Claims 1 and 5-7 are rejected under 35 U.S.C. 102(b) as anticipated by Wu et al *(FEBS Letters 439 (1998), p. 192-196).*

Claims 1 and 5-7 are drawn to a pharmaceutical composition and vaccine for vaccination comprising a bacterial Cu, Zn superoxide dismutase (Cu,Zn-SOD) of the dimeric type, or a fragment, variant or derivative of the Cu,Zn-SOD wherein antibodies raised against said fragment, variant or derivative also bind intact full-length Cu,Zn-SOD or a nucleic acid coding for the Cu,Zn-SOD fragment, variant or derivative and a pharmaceutically acceptable carrier.

Wu et al teach purified Cu,Zn superoxide dismutase of *Mycobacterium tuberculosis* (see the Title). Wu et al teach a pharmaceutical composition comprising a purified M-sodC protein in the acrlyamide gel were mixed with complete Freund adjuvant used to immunize 3 month old New Zealand White rabbits followed by three boosts with proteins mixed in incomplete Freund adjuvant (page 193, 1st column).

Since the Office does not have the facilities for examining and comparing applicant's pharmaceutical composition and vaccine with the pharmaceutical composition and vaccine of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the pharmaceutical composition and vaccine of the prior art does not possess

the same material structural and functional characteristics of the claimed pharmaceutical composition and vaccine). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

9. Claim 9 is rejected under 35 U.S.C. 102(b) as anticipated by Wu et al *(FEBS Letters 439 (1998), p. 192-196).*

Claim 9 is drawn to a method of preparing a pharmaceutical composition isolating a gene for a bacterial Cu, Zn-superoxide dismutase (Cu,Zn-SOD) of the dimeric type, or a fragment, variant or derivative of the Cu, Zn-SOD wherein antibodies raised against said fragment, variant or derivative also bind intact full-length Cu,Zn-SOD; and synthesizing the Cu,Zn-SOD or fragment, variant or derivative from gene; and combining said Cu,Zn-SOD, fragment, variant or derivative with a pharmaceutically acceptable or combining said gene with a pharmaceutically acceptable carrier.

Wu et al teach a method of preparing a pharmaceutical composition comprising isolating and synthesizing the gene for bacterial Cu, Zn-superoxide dismutase (Cu,Zn-SOD) of the dimeric type (pages 193-194).

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

10. Claim 10 is rejected under 35 U.S.C. 102(b) as anticipated by Wu et al *(FEBS Letters 439 (1998), p. 192-196).*

Claim 10 is drawn to a pharmaceutical composition comprising an antibody to a bacterial Cu, Zn superoxide dismutase (Cu,Zn-SOD) of the dimeric type, or a fragment, variant or derivative of the Cu,Zn-SOD wherein antibodies raised against said fragment, variant or derivative also bind intact full-length Cu,Zn-SOD or a nucleic acid coding for the Cu,Zn-SOD fragment, variant or derivative and a pharmaceutically acceptable carrier.

Wu et al teach antisera raised against the recombinant *M. tuberculosis* Cu,ZnSOD allowed for the detection of a single polypeptide lysate of *M. tuberculosis* (see the Abstract and page 193, 1st column). The pharmaceutically acceptable carrier would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's pharmaceutical composition with the pharmaceutical composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the pharmaceutical composition of the prior art does not possess the same material structural and functional characteristics of the claimed pharmaceutical composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of Claims

11. No claims are allowed.

Conclusion

12. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
June 10, 2003

JAMES O. WILSON
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